PSJ3

Exhibit 669

U.S. Supreme Court

DIRECT SALES CO. v. UNITED STATES, 319 U.S. 703 (1943)

319 U.S. 703

DIRECT SALES CO., Inc.,
v.
UNITED STATES.
No. 593.

Argued April 12, 1943.
Decided June 14, 1943.

[319 U.S. 703, 704] Mr. Wm. B. Mahoney, of Buffalo, N.Y., for petitioner.

Mr. Valentine Brookes, of Washington, D.C., for respondent.

Mr. Justice RUTLEDGE delivered the opinion of the Court.

Petitioner, a corporation, was convicted of conspiracy to violate the Harrison Narcotic Act. 1 It challenges the sufficiency of the evidence to sustain the conviction. Because of asserted conflict with United States v. Falcone, 311 U.S. 205, 61 S.Ct. 204, certiorari was granted.

Petitioner is a registered drug manufacturer and wholesaler. 2 It conducts a nationwide mail-order business from Buffalo, New York. The evidence relates chiefly to its transactions with one Dr. John V. Tate and his dealings with others. He was a registered physician, practicing in Calhoun Falls, South Carolina, a community of about 2000 persons. He dispensed illegally vast quantities of morphine sulphate purchased by mail from petitioner. The indictment charged petitioner, Dr. Tate, and three others, Black, Johnson and Foster, to and through whom Tate illegally distributed the drugs, with conspiring to violate [319 U.S. 703, 705] Sections 1 and 2 of the Act,3 over a period extending from 1933 to 1940. Foster was granted a severance, Black and Johnson pleaded guilty, and petitioner and Dr. Tate were convicted. Direct Sales alone appealed. The Circuit Court of Appeals affirmed. 131 F.2d 835.

The parties here are at odds concerning the effect of the Falcone decision as applied to the facts proved in this case. The salient facts are that Direct Sales sold morphine sulphate to Dr. Tate in such quantities, so frequently and over so long a period it must have known he could not dispense the amounts received in lawful practice and was therefore distributing the drug illegally. Not only so, but it actively stimulated Tate's purchases.

He was a small-town physician practicing in a rural section. All of his business with Direct Sales was done by mail. Through its catalogues petitioner first made [319 U.S. 703, 706] contact with him prior to 1933. Originally he purchased a variety of pharmaceuticals. But gradually the character of his purchases narrowed, so that during the last two years of the period alleged for the conspiracy he ordered almost nothing but morphine sulphate. At all times during the period he purchased the major portion of his morphine sulphate from petitioner. The orders were made regularly on his official order forms. The testimony shows the average physician in the United States does not require more than 400 one-quarter grain tablets annually for legitimate use. Although Tate's initial purchases in 1933 were smaller, they

gradually increased until, from November, 1937, to January, 1940, they amounted to 79,000 one-half grain tablets. In the last six months of 1939, petitioner's shipments to him averaged 5,000 to 6,000 half-grain tablets a month, enough as the Government points out to enable him to give 400 average doses every day.

These quantity sales were in line with the general mail-order character of petitioner's business. By printed catalogues circulated about three times a month, it solicits orders from retail druggists and physicians located for the most part in small towns throughout the country. Of annual sales of from $300,000 to $350,000 in the period 1936 to 1940, about fifteen per cent by revenue and two-and-a-half per cent by volume were in narcotics. he mail- order plan enabled petitioner to sell at prices considerably lower than were charged by its larger competitors, who maintained sales forces and traveling representatives. By offering fifty per cent discounts on narcotics, it 'pushed' quantity sales. Instead of listing narcotics, like morphine sulphate, in quantities not exceeding 100 tablets, as did many competitors, Direct Sales for some time listed them in 500, 1000 and 5000 tablet units. By this policy it attracted customers, including a dispropor- [319 U.S. 703, 707] tionately large group of physicians who had been convicted of violating the Harrison Act.

All this was not without warning, purpose or design. In 1936 the Bureau of Narcotics informed petitioner it was being used as a source of supply by convicted physicians. 4 The same agent also warned that the average physician would order no more than 200 to 400 quarter-grain tablets annually5 and requested it to eliminate the listing of 5000 lots. It did so, but continued the 1000 and 500 lot listings at attractive discounts. It filled no more orders from Tate for more than 1000 tablets, but continued to supply him for that amount at half-grain strength. On one occasion in 1939 he ordered on one form 1000 half and 100 quarter grains. Petitioner sent him the 1000 and advised him to reorder the 100 on a separate order form. It attached to this letter a sticker printed in red suggesting anticipation of future needs and taking advantage of discounts offered. Three days later Tate ordered 1000 more tablets, which petitioner sent out. In 1940, at the Bureau's suggestion, Direct Sales eliminated its fifty and ten per cent discounts. But on doing so it translated its discount into its net price.

Tate distributed the drugs to and through addicts and purveyors, including Johnson, Black and Foster. Although he purchased from petitioner at less than two dol- [319 U.S. 703, 708] lars, he sold at prices ranging from four to eight dollars per 100 half- grain tablets and purveyors from him charged addicts as much as $25 per hundred.

On this evidence, the Government insists the case is in different posture from that presented in United States v. Falcone. It urges that the effort there was to connect the respondents with a conspiracy between the distillers on the basis of the aiding and abetting statute. 6 The attempt failed because the Court held the evidence did not establish the respondents knew of the distillers' conspiracy. There was no attempt to link the supplier and the distiller in a conspiracy inter sese. But in this case that type of problem is presented. Direct Sales was tried, and its conviction has been sustained, according to the claim, on the theory it could be convicted only if it were found that it and Tate conspired together to subvert the order form provisions of the Harrison Act. As the brief puts the Government's view, 'Petitioner's guilt was not made to depend at all upon any guilt of Dr. Tate growing out of his relationship to defendants other than petitioner or upon whether these other defendants were linked with the Tate-Direct Sales conspiracy.'

On the other hand, petitioner asserts this case falls squarely within the facts and the ruling in the Falcone case. It insists there is no more to show conspiracy between itself and Tate than there was to show conspiracy between the respondent sellers and the purchasing distillers there. At most, it urges, here were only legal sales by itself to Dr. Tate, accompanied by knowledge he was distributing goods illegally. But this, it contends, cannot amount to conspiracy on its part with him, since in the Falcone case the respondents sold to the distillers, knowing they would use the goods in illegal distillation. [319 U.S. 703, 709] Petitioner obviously misconstrues the effect of the Falcone decision in one respect. This is

in regarding it as deciding that one who sells to another with knowledge that the buyer will use the article for an illegal purpose cannot, under any circumstances, be found guilty of conspiracy with the buyer to further his illegal end. The assumption seems to be that, under the ruling, so long as the seller does not know there is a conspiracy between the buyer and others, he cannot be guilty of conspiring with the buyer, to further the latter's illegal and known intended use, by selling goods to him.

The Falcone case creates no such sweeping insulation for sellers to known illicit users. That decision comes down merely to this, that one does not become a party to a conspiracy by aiding and abetting it, through sales of supplies or otherwise, unless he knows of the conspiracy; and the inference of such knowledge cannot be drawn merely from knowledge the buyer will use the goods illegally. The Government did not contend, in those circumstances, as the opinion points out, that there was a conspiracy between the buyer and the seller alone. It conceded that on the evidence neither the act of supplying itself nor the other proof was of such a character as imported an agreement or concert of action between the buyer and the seller amounting to conspiracy. This was true, notwithstanding some of the respondents could be taken to know their customers would use the purchased goods in illegal distillation.

The scope of the concession must be measured in the light of the evidence with reference to which it was made. This related to both the volume of the sales and to casual and unexplained meetings of some of the respondents with others who were convicted as conspirators. The Court found this evidence too vague and uncertain to support a finding the respondents knew of the distillers' conspiracy, [319 U.S. 703, 710] though not inadequate in some instances to sustain one that the seller knew the buyer would use the goods for illegal distilling. It must be taken also that the Government regarded the same evidence as insufficient to show the seller conspired directly with the buyer, by selling to him with knowledge of his intended illegal use.

Whether or not it was consistent in making this concession and in regarding the same evidence as sufficient to show that the sellers knew of and joined the buyers' distilling ring is not material. Nor need it be determined whether the Government conceded too much. We do not now undertaken to say what the Court was not asked and therefore declined to say in the Falcone case, namely, that the evidence presented in that case was sufficient to sustain a finding of conspiracy between the seller and the buyer inter sese. For, regardless of that, the facts proved in this case show much more than the evidence did there.

The commodities sold there were articles of free commerce, sugar, cans, etc. They were not restricted as to sale by order form, registration, or other requirements. When they left the seller's stock and passed to the purchaser's hands, they were not in themselves restricted commodities, incapable of further legal use except by compliance with rigid regulations, such as apply to morphine sulphate. The difference is like that between toy pistols or hunting rifles and machine guns. All articles of commerce may be put to illegal ends. But all do not have inherently the sam susceptibility to harmful and illegal use. Nor, by the same token, do all embody the same capacity, from their very nature, for giving the seller notice the buyer will use them unlawfully. Gangsters, not hunters or small boys, comprise the normal private market for machine guns. So drug addicts furnish the normal outlet for morphine which gets outside the restricted channels of legitimate trade. [319 U.S. 703, 711] This difference is important for two purposes. One is for making certain that the seller knows the buyer's intended illegal use. The other is to show that by the sale he intends to further, promote and cooperate in it. This intent, when given effect by overt act, is the gist of conspiracy. While it is not identical with mere knowledge that another purposes unlawful action, it is not unrelated to such knowledge. Without the knowledge, the intent cannot exist. United States v. Falcone, supra. 7 Furthermore, to establish the intent, the evidence of knowledge must be clear, not equivocal. Ibid, This, because charges of conspiracy are not to be made out by piling inference upon inference, thus fashioning what, in that case, was called a dragnet to draw in all substantive crimes.

The difference between sugar, cans, and other articles of normal trade, on the one hand, and narcotic drugs, machine guns and such restricted commodities, on the other, arising from the latters' inherent capacity for harm and from the very fact they are restricted, makes a difference in the quantity of proof required to show knowledge that the buyer will utilize the article unlawfully. Additional facts, such as quantity sales, high pressure sales methods, abnormal increases in the size of the buyer's purchases, etc., which would be wholly innocuous or not more than ground for suspicion in relation to unrestricted goods, may furnish conclusive evidence, in respect to restricted articles, that the seller knows the buyer has an illegal object and enterprise. Knowledge, equivocal and uncertain as to one, becomes sure as to the other. So far as knowl- [319 U.S. 703, 712] edge is the foundation of intent, the latter thereby also becomes the more secure.

The difference in the commodities has a further bearing upon the existence and the proof of intent. There may be circumstances in which the evidence of knowledge is clear, yet the further step of finding the required intent cannot be taken. Concededly, not every instance of sale of restricted goods, harmful as are opiates, in which the seller knows the buyer intends to use them unlawfully, will support a charge of conspiracy. 8 But this is not to say that a seller of harmful restricted goods has license to sell in unlimited quantities, to stimulate such sales by all the high-pressure methods, legal if not always appropriate, in the sale of free commodities; and thereby bring about subversion of the other forms, which otherwise would protect him, and violation of the Act's other restrictions. Such a view would assume that the market for opiates may be developed as any other market. But that is not true. Mass advertising and bargain counter discounts are not appropriate to commodities so surrounded with restrictions. They do not create new legal demand and new classes of legitimare patrons, as they do for sugar, tobacco and other free commodities. Beyond narrow limits, the normal legal market for opiates is not capable of being extended by such methods. The primary effect is rather to create black markets for dope and to increase illegal demand and consumption. [319 U.S. 703, 713] When the evidence discloses such a system, working in prolonged cooperation with a physician's unlawful purpose to supply him with his stock in trade for his illicit enterprise, there is no legal obstacle to finding that the supplier not only knows and acquiesces, but joins both mind and hand with him to make its accomplishment possible. The step from knowledge to intent and agreement may be taken. There is more than suspicion, more than knowledge, acquiescence, carelessness, indifference, lack of concern. There is informed and interested cooperation, stimulation, instigation. And there is also a 'stake in the venture' which, even if it may not be essential, is not irrelevant to the question of conspiracy. 9 Petitioner's stake here was in making the profits which it knew could come only from its encouragement of Tate's illicit operations. In such a posture the case does not fall doubtfully outside either the shadowy border between lawful co-operation and criminal association or the no less elusive line which separates conspiracy from overlapping forms of criminal cooperation.

Unless, therefore, petitioner has been exempted arbitrarily by the statute's terms, the evidence clearly was sufficient to sustain its conviction for conspiring with Tate. Its position here comes down ultimately to the view alluded to above that the statute has, in fact, thus immunized its action. In effect this means the only restriction imposed upon it, apart from other provisions not now material, such as those affecting registration, was the requirement it should receive from purchasing physicians a signed order form for each sale. That done, in its view, its full duty to the law was fulfilled, it acquired a complete immunity, and what the physician had done [319 U.S. 703, 714] or might do with the drugs became of no further concern to itself. Such a view would legalize an express written agreement between a registered wholesaler and a physician for the former to supply him with all his requirements for drugs for both legal and illegal distribution, conditioned only upon his using the required order forms. The statute contains no such exemption in explicit terms. Nor was one implied. 10

This being true, it can make no difference the agreement was a tacit understanding, created by a long course of conduct and executed in the same way. 11 Not the form or manner in which the understanding is made, but the fact of its existene and the further one of making it effective by overt conduct are the crucial matters. The proof, by the very nature of the crime, must be circumstantial12 and therefore

inferential to an extent varying with the conditions under which the crime may be committed. But this does not mean either that the evidence may be equivocal or that petitioner is exempt from its effects when it is not so, merely because in the absence of excesses such as were committed and in other circumstances the order form would have given it protection. It follows the mere fact that none of petitioner's representatives ever met Dr. Tate face to face or held personal communion with him is immaterial. Conspiracies, in short, can be committed by mail and by mail-order houses. This is true, n twithstanding the overt acts consist solely of sales, which but for their volume, frequency and prolonged [319 U.S. 703, 715] repetition, coupled with the seller's unlawful intent to further the buyer's project, would be wholly lawful transactions.

Accordingly, the judgment is

Affirmed.

Footnotes

[Footnote 1] The conspiracy statute, R.S. 5440, as amended, 18 U.S.C. 88, provides:

> 'If two or more persons conspire either to commit any offense against the United States, or to defraud the United States in any manner or for any purpose, and one or more of such parties do any act to effect the object of the conspiracy, each of the parties to such conspiracy shall be fined not more than $10,000, or imprisoned not more than two years, or both.'

The pertinent provisions of the Harrison Act are set out in note 3, infra.

[Footnote 2] 38 Stat. 785, as amended, 26 U.S.C. 3220, 3221.

[Footnote 3] 38 Stat. 785, as amended, 26 U.S.C. 2553, 2554. The indictment charged the conspiracy's object was to violate those portions of the Act (as amended) which provide:

> 'It shall be unlawful for any person required to register under the provisions of this part or section 2551(a) to import, manufacture, produce, compound, sell, deal in, dispense, distribute, administer, or give away any of the aforesaid drugs without having registered and paid the special tax as imposed by this part, or section 2551(a).' 26 U.S.C. 3224.
>
> 'It shall be unlawful for any person to purchase, sell, dispense, or distribute any of the drugs mentioned in section 2550(a) except in the original stamped package or from the original stamped package ....' 26 U. S.C. 2553.
>
> 'It shall be unlawful for any person to sell, barter, exchange, or give away any of the drugs mentioned in section 2550(a) except in pursuance of a written order of the person to whom such article is sold, bartered, exchanged, or given, on a form to be issued in blank for that purpose by the Secretary.' 26 U.S.C. 2554(a).
>
> 'It shall be unlawful for any person to obtain by means of said order forms any of the aforesaid drugs for any purpose other than the use, sale, or distribution thereof by him in the conduct of a lawful business in said drugs or in the legitimate practice of his profession.' 26 U.S.C. 2554(g).

[Footnote 4] Thus, although there were more than 1350 wholesale drug dealers in the United States rom whom physicians might order narcotics (Traffic in Opium and Other Dangerous Drugs for the Year Ended December 31, 1941, United States Treasury, Bureau of Narcotics), about 27% of the 204 doctors convicted were petitioner's customers.

[Footnote 5] Testimony in the record establishes that the practice in the profession is to give one-eighth or one-fourth grain doses, and only rarely one-half grain doses. Cf. United States v. Behrman, 258 U.S. 280, 289 , 42 S.Ct. 303, 305. Furthermore, there was expert testimony to the effect that codein may be, and preferably is, used for the same medical purposes as morphine sulphate. During the period from 1934 to 1940, however, the record does not show that Tate ever ordered codein from petitioner.

[Footnote 6] R.S. 5323, 18 U.S.C. 550.

[Footnote 7] Although this principle was there applied to aiding and abetting a conspiracy among others, it has at least equal force in a situation where the charge is conspiring with another to further his unlawful conduct, without reference to any conspiracy between him and third persons.

[Footnote 8] This may be true, for instance, of single or casual transactions, not amounting to a course of business, regular, sustained and prolonged, and involving nothing more on the seller's part than indifference to the buyer's illegal purpose and passive acquiescence in his desire to purchase, for whatever end. A considerable degree of carelessness coupled with casual transactions is tolerable outside the boundary of conspiracy. There may be also a fairly broad latitude of immunity for a more continuous course of sales, made either with strong suspicion of the buyer's wrongful use or with knowledge, but without stimulation or active incitement to purchase.

[Footnote 9] Cf. United States v. Falcone, 2 Cir., 109 F.2d 579, 581; and compare Backun v. United States, 4 Cir., 112 F.2d 635, 637; United States v. Harrison, 3 Cir., 121 F.2d 930, 933; United States v. Pecoraro, 2 Cir., 115 F.2d 245, 246.

[Footnote 10] Cf. Gebardi v. United States, 287 U.S. 112 , 53 S.Ct. 35, 84 A.L.R. 370; see also 81 U. of Pa.L.Rev. 474.

[Footnote 11] Glasser v. United States, 315 U.S. 60, 80 , 62 S.Ct. 457, 469; United States v. Manton, 107 F.2d 834, 839; United States v. Harrison, 3 Cir., 121 F.2d 930, 934; Eastern States Retail Lumber Dealers' Ass'n v. United States, 234 U.S. 600 , 34 S.Ct. 951, L.R.A. 1915A, 788; Interstate Circuit, Inc., v. United States, 306 U.S. 208 , 59 S. Ct. 467.

[Footnote 12] Ibid.

Giacalone, Robert

From: McPherson, Carolyn
Sent: Wednesday, October 10, 2007 8:34 AM
To: Giacalone, Robert
Cc: Cacciatore, Gary; Reardon, Steve
Subject: RE: DEA

Confidential: Subject to Attorney-Client Privilege and Work Product Doctrines

Answers I have so far – will followup with info on IT timeline after the mtg at 3PM tomorrow.

2. 18 pharmacies are being visited – projected to complete by end of week. 7 of those pharmacies have been cut off completely from Hydrocodone or Oxycodone orders until after the audit and approval from corporate QRA has been received to resume. Remaining pharmacies are part of a process to hold their orders for Hydro/oxy and have one of 2 managers in the Houston DC group drugs into the 2 categories and then cut the orders to max of 1000 dosage units for each group (hydrocodone and oxycodone). All other drugs for these customers and all controlled substance drugs for remainder of Houston customers are subject to the DC's standard use of the Dosage Limit Chart and their rules they have been using to cut orders.

Interviews have been completed for all other HSCS-P DCs on what they are doing to monitor/cut orders and what their use of the Dosage Limit Chart has been. Interview notes are being documented.

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From: Giacalone, Robert
Sent: Wednesday, October 10, 2007 8:14 AM
To: Reardon, Steve; McPherson, Carolyn
Cc: Cacciatore, Gary
Subject: DEA

Confidential: Subject to Attorney-Client Privilege and Work Product Doctrines

Steve/Carolyn:

I know you and your team are working diligently on a remediation plan, but if I intend to meet with the DEA (ideally) next week, I'll need to know the following:

(1) What is our projected timeline for a solution - beta and final. Also, generally, what does that concept envision (i.e., how does it work and where does it address those issues we and DEA identified)?
(2) What exactly are we doing in the interim? For example, how many pharmacies have we visited in the top 25 hydrocodone accounts as a follow up? When do we expect the rest of the visits completed? Have we contacted the other DC's to see how they are handling excessive purchase orders? Is it similar to Houston? What else are we doing in Houston?
(3) I would plan on bringing in the pharmacy checklist, the Internet presentation to the meeting. Any other things you thing may be worth bringing?\

Thanks, Bob.

NOTE: It is DEA's policy that if a state agency having jurisdiction over wholesalers has adopted disposal procedures for controlled substances, the wholesaler may follow these procedures in lieu of DEA requirements.

b.) Destruction of ARCOS reportable items filed on **DEA Form 41** must also be submitted to ARCOS.

c.) Unsaleable merchandise may be sent to third party firms for destruction.

i.) The facility must create a Debit Memo to the third-party firm.

ii.) Third-party firm destroys the product and files the **DEA Form 41.**

d.) **DEA Form 41** shall be used for documenting a non-recoverable liquid controlled substance loss when the container accidentally breaks.

i.) Pieces of the broken bottle do not need to be retained as evidence of the accident.

ii) Any loss of an ARCOS reportable item must also be reported to ARCOS using code Y and the local DEA field office's DEA number.

iii) **Do Not Submit the 41 to DEA.**

5.) Suspicious orders

a.) Wholesalers must design and operate a system that will disclose suspicious orders to the wholesaler.

i.) The facility must inform the DEA field office in the area of all suspicious orders.

ii.) Suspicious orders include orders of unusual size, orders deviating from a normal pattern and orders of unusual frequency.

b.) Wholesalers must establish written criteria of what constitutes a suspicious order.

i.) The criteria must be reasonable and based upon customer purchasing patterns.

ii.) Each facility must adhere to the established criteria in monitoring orders.

iii.) Monitoring system may be either computerized or manual.

c.) Each facility shall submit to the local DEA office on a monthly basis, via registered or certified mail, return receipt requested, or via Federal Express or UPS with a tracking number, an Ingredient Limit Report **(Exhibit EC04.00)**.

NOTE: The report is based on a computer program which monitors customer controlled substance purchases for a month and compares these purchases to predetermined averages or limits and if a customer's purchase quantities exceed the established parameters, the customer's activity is printed on the report.

d.) On a daily basis, each facility shall monitor and identify individual orders that appear excessive in relation to what other customers are buying and/or the customer's purchase history.

i.) The facility shall notify the local DEA field office, if possible before the order is shipped.

ii.) A copy of all such orders must be maintained in the facility's suspicious order file.

iii.) A Regulatory Agency Contact Form **(Form FC04.00)** must be completed, noting any specific instructions from the DEA.

e.) Dosage Limit Charts **(Exhibit ED04.00)** must be posted in the cage and vault.

f.) Each location for the products listed on the charts shall be marked with the hospital and retail dosage limits.

Summary of the DEA-HDMA Meeting on Suspicious Orders
Meeting Date: Sept. 7, 2007

HDMA Attendees: Scott Melville, Anita Ducca, David Durkin (OFW)

DEA Attendees: Mark Caverly, Kathy Gallagher, Mike Mapes, Lisa Sullivan

Summary: After introductions, HDMA

- Gave a brief overview of the Association, the Distribution industry, and described some of HDMA's safety policies and initiatives.
- Indicated our interest in having the DEA explain their "Internet Distributor Initiative" and understanding the DEA's expectations.

DEA then provided us with their latest organization chart and explained the responsibilities of each section. Mike Mapes then provided HDMA with the same presentation that DEA has provided to several wholesale distributors regarding suspicious orders. (Attached) He noted that DEA had met with approximately 15-20 wholesale distributors one-on-one. They had prioritized who to meet with on a combination of wholesale distributor sales volume and tracing back to where they felt the source of products for illicit Internet pharmacies were located.

Key "take aways" from the meeting were:

- DEA's policy was to expect more than just reporting "suspicious orders". If there was a suspicious order, the distributor should either stop the delivery or should evaluate the customer further before delivering it.
- Simply complying with the "suspicious orders" regulatory requirement does *not* mean, in the agency's view, that the registrant is maintaining an effective program to detect and prevent diversion.
- DEA indicated that they did not have the resources to inspect every pharmacy; therefore it was important for the distributor to "know their customers."
- The DEA criteria reflected in their September 2006 letter to registrants was "for background" and they do not expect the wholesale distributor to violate privacy or other laws to find out what they needed to know about their customers.

Additional points DEA made included:

- DEA was clear that the "system" mentioned above did not need to be the same for each wholesale distributor.
- DEA provided examples of what a wholesale distributor should do to "know their customers" and what to look for. For example, they mentioned inspecting pharmacies. They also mentioned such actions as "doing Google searches" to determine if the pharmacy's name was affiliated with an internet site, and getting information from the state as to the nature and number of prior legal actions against a pharmacy. And they gave a checklist of "Internet Pharmacy Decision Questions" meant as a guide. (See attachment

– page 2 after the organization chart) However, they did not give specifics as to how to go about completing the checklist beyond the examples above, and it was unclear if they expected wholesale distributors to inspect all pharmacies

- DEA also does not want to receive suspicious order reports that merely reflect volumes that went over a threshold; they wanted reports that are "true" suspicious orders. Similarly, they do not want to receive what they called "excessive purchase" reports which had been used in the past.
- DEA also indicated that they were not going to make a decision for the wholesale distributor as to when an order was "suspicious". They feel this is up to the distributor.
- DEA suggested that distributors should check on the pharmacy's prescribing physicians. They pointed to some states having on-line systems by which a distributor could check to see if a prescribing physician had a valid DEA registration. DEA suggested that distributors ask who the doctors are that are prescribing, where the pharmacy is geographically with respect to its prescribing doctors and the patient population.

Conclusion:

At the close of the meeting, HDMA indicated that we would be meeting with our members and discussing this further. We indicated that we might be suggesting future meetings between our two organizations and our members.

HDMA questions and assessment:

- DEA attempted to place the Sept. 2006 letter into a better light than what it appeared to be on its face.
- DEA's expectations are clearly heightened. HDMA would like to ask its members about the impact of these expectations. For example,
    - Are all members capable of inspecting their pharmacy customers?
    - How difficult is it to put a "system" in place that not only monitors suspicious orders but also stops the order and/or evaluates the customer against the order?
    - How often does a suspicious order fall into a "gray area" for example, the order is larger than a pre-established threshold, but not so far over that it is clearly out of line with that pharmacy's customer base and size?

- Do we need better clarification and/or a written statement from the DEA about when to send a suspicious order and when not to send it even if it is over a threshold?
- Do we have recommendations for DEA as to how to approach this problem in a way that simplifies things for the wholesale distributor? Would some of our anti-counterfeit policies fit this situation? E.g., ask them to support RFID? Recommend, (and press for) better pharmacy inspections by DEA prior to licensure?